HIGH PERFORMANCE COIL WIRE

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A high performance coil over-core guide wire. The guide wire incorporates a nickel-titanium core with a stainless steel coil to provide a wire with improved kink resistance and good pushability.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
(Field of an invention)
This invention generally relates to guidewires and those manufacturing methods. In detail, this invention is produced from an inner substance core, and relates to the guidewire enclosed by the coil. A person skilled in the art recognizes the advantage which applies this invention to the similar field which is not indicated on these Descriptions.
[0002]
(The background of an invention)
A guidewire is used for various medical-application uses containing a gastrointestinal tract and the urinary organs in a blood vessel. The usual blood vessel use is endermic transluminal coronary circulation formation (Percutaneous Transluminal Coronary Angioplasty) (PTCA). This procedure includes the process which crosses the focus which deals with the heart to coronary arteries, and is made to follow a guidewire to them exceeding the process and aortic arch which insert a guidewire through incision of the femoral artery near the ******. Similarly, the angiogensis performed by the anatomy in other portions is called endermic transluminal angiogensis (PTA), and may include use of a guidewire again. A typical blood vessel guidewire is 50 cm or 300 cm in length depending on a use, and is 0.010-0.038 inch in diameter.
[0003]
Including an endoscope procedure, an endoscope is inserted in a mouth and the use by the gastrointestinal tract of the usual guidewire follows it to a bile duct, a cystic duct, or a pancreatic duct through an esophagus here. A guidewire ranks second, passes along the lumen of an endoscope, and it lets it pass to a bile duct, a cystic duct, or a pancreatic duct. If arranged at the position once expected to deal with the distance tip of a guidewire, the catheter which has medical-application apparatus in the distal end will be carried forward to a treatment field exceeding a guidewire. Subsequently, a guidewire and a catheter may be observed through an endoscope, when treatment is performed.
[0004]
The use by the urinary organs of a guidewire includes arrangement of the ureter stent. The stent deployment of a ureter is needed when the usual flow of the urine from the kidney to a bladder is probably spoiled with tumor growth, strangulation, or a calculus. Generally, this procedure

includes insertion of the urethroscope (ureteroscope) to the bladder which passes along an urethra. Subsequently, a guidewire passes along the urethroscope and follows it to a ureter. Subsequently, it is forced a wire so that it may pass along the portion by which the ureter was harmed. If a guidewire is put on a proper place, the ureter stent will once be carried forward to the position of a ureter exceeding a guidewire. Subsequently, a guidewire may be removed and the stent maintains the patency of the channel between the kidney and a bladder. However, the above-mentioned procedure is mere a few of the publicly known use of a guidewire.

[0005]

Pushing capability, twist-proof nature, torque capacity, and flexibility are the important features which relate to a guidewire closely. It is important that the power applied to the proximal end part of a guidewire is thoroughly transmitted to the distal end of a guidewire. Although a very hard wire often provides good pushing capability (axial rigidity), it provides scarce twist-proof nature. Twist-proof nature is measured by the capability of the guidewire which a have [no modification of an eternal wire] comparatively small (tight) crookedness radius is forced. The guidewire must show good flexibility. This feature is the balance between the suitable rigidity for supporting imitation (tracking) of another device like the suitable flexibility for navigating the lumen which wound, and a catheter. Torque capacity relates to the torsional rigidity of a guidewire closely, and it is shown ultimately how the rotation given to the proximal end part of a guidewire is fully transmitted to the distal end of a guidewire.

[0006]

The conventional guidewire is produced from carbon steel or stainless steel. These days, the superelastic alloy (super-elastic alloys) guidewire was used more. Superelasticity or a false elastic metal guidewire was taught to US,4,925,445,B of Sakamoto. Use of the elastic alloy was taught in US,5,238,004,B of Sahatjian, and 5,230,348 of Ishibe. It teaches that No. 5,238,004 of Sahatjian may be used in order that it may be further heat-treated in order that elastic metal may form crookedness in a wire core, and core-less grinding may produce a specific wire profile.

[0007]

Some different guidewires are well-known in the field concerned. One kind of wire is characterized by the inner substance metal core surrounded with the metal coil. As for the typical metal of a core, spring steel and stainless steel may be contained. The distance tip of a core may be ground by the taper again, in order to provide the further flexibility near the tip. A coil may be produced from the metal of the same kind used as core materials. A coil may be produced from a circular wire or a flat wire, and can enclose the overall length of a core, or a part of core. A coil is usually formed rolling the surroundings of an axis spirally with a wire, removing an axis, and by inserting a core in a coil. The pitch of a wire may change along with the length of a coil in order to change the hardness of a coil.

[0008]

A highly efficient guidewire usually has high twist-proof nature and outstanding wire movement. The fundamental composition of a highly efficient wire is the Nitinol (Nitinol) core enclosed by lubricative coating. Since Nitinol of high elasticity absorbs some of power given to the proximal end part of the wire to an unfortunate thing, to it, the Nitinol guidewire wears the pushing capability to have decreased. The improved highly efficient wire provides better pushing capability to the conventional superelasticity wire.

[0009]

The traditional coil which covers a core wire provides good axial hardness, therefore the improved pushing capability. The traditional coil which covers a core wire provides again the

twist-proof nature dramatically improved about the stainless steel wire. However, since a coil will tend to be rolled if torque starts, there is a tendency to provide the torque convectivity in which the wrap coil decreased the core wire. Therefore, it is advantageous to provide a wrap coil for the core wire which has the torque convectivity of a highly efficient wire.

[0010]

(Gist of an invention)

This invention conquers the fault of the advanced technology by providing a wrap coil for the core guide wire which has the torque convectivity of a wrap coil for wire movement of twist-proof nature and a superelasticity wire, pushing capability, and a core wire. A guidewire has a nickel titanium alloy core provided with a tapered shape distance tip. A core may be superelasticity or straight-line elasticity (linear-elastic).

[0011]

A coil encloses most cores and may be combined with a core. A coil may be stainless steel or nickel titanium. A coil may be a coil which might be produced from a flat wire or circular wire, might be produced from the single strand or the strand of many textiles (multifilar), and was wound around a single coil or intersection.

[0012]

A guidewire can be provided with the polymer tip to which radiopacity material can be attached further. A wire may be coated with lubricative coating again. The polymer nature tip can form a pliant (floppy) tip without a safe ribbon.

[0013]

(DETAILED DESCRIPTION)

The following detailed explanation should be read with reference of the Drawings in which the similar element in different Drawings has a number given similarly. Drawings show not fixed proportionality but the selected embodiment, and do not necessarily mean restricting the scope of an invention.

[0014]

Composition, material, a size, and the example of a manufacturing process are provided about the selected element. Other elements of all the use a publicly known thing for the person skilled in the art of the field of this invention concerned. a person skilled in the art has a suitable substitute with which many examples provided may be used -- thing recognition is carried out.

[0015]

Drawing 1 shows the 1st working example of the guidewire 10. The core 20 is 50-450 cm in length depending on the use of medical application, and may be 0.008-0.038 inch in diameter. The distance portion 25 of the core 20 may be made into tapered shape in order to provide the guidewire 10 with flexibility. Preferably, the tapered shape distance portion 25 is formed by grinding 5-20 cm of the core 20. The tapered shape distance portion 25 may be pierced so that it may be ground by the cone shape which has a circle section or may have a ** type section (stamp).

[0016]

The core 20 may be produced from a hyperelastic material like the alloy (publicly known [generally] as Nitinol) of nickel and titanium. Although Nitinol is a usual hyperelastic material most, the arbitration of other various hyperelastic materials may be used to the core 20. :CuAlNi, CuSn, CuZn, InTi, NiAl, FePt, MnCu, and FeMnSi by which the following is mentioned to other alloys by a chemical name. US,4,925,445,B of Sakamoto is provided with explanation detailed to a superelastic alloy, and those processings, and they are used as reference into this Description.

[0017]
In addition to a hyperelastic material, a straight-line spring material may be used. A straight-line spring material is indicated to US,5,238,004,B of Sahatjian, and this is also used as reference. Generally, a straight-line spring material comprises same above-mentioned alloy. However, the strategy of processing of various materials is used in order to provide the wire which has many of important features of a hyperelastic material which do not have difficult some relevant to machining (it grinds especially). Thus, the core 20 may be preferably formed from the straight-line spring material of nickel titanium.
[0018]
The coil 30 encloses the core 20. In the field concerned, a wrap coil is well-known, it is indicated to US,5,147,317,B of Shank in detail, and a core wire is used for it as reference. From various metallic materials, the coil 30 may be produced and to this. Superelasticity or a straight-line spring material (for example, Nitinol), radiopacity material (for example, gold or tungsten), A precipitation-hardening alloy (for example, alloy MP35N of a non-iron cobalt base or Elgiloy (registered trademark), and an iron alloy (K91 and PH455 from Carpenter from Sanvic Corp.)) or the more conventional stainless steel alloy (for example, 304) is mentioned. Preferably, the coil 30 may be 0.001-0.015 inch in diameter, and may be produced from 304 stainless steel.
[0019]
The coil 30 is wound around the real target of the core 20 around an overall length. Preferably, the coil 30 is not rolled around the tapered shape distance portion 25 of the core 20. The coil 30 may be produced from the flat ribbon of the range of a size with a thickness of 0.001-0.003 inch, and a width of 0.005-0.015 inch. The surroundings of the core 20 are wound around the coil 30 in a spiral form by the conventional volume art. A pitch may be set up so that it may be wound around the surroundings of the core 20 with the open form with which the pitch of the turn which the coil 30 adjoins may be strongly rolled so that each turn may touch on the next turn, or the coil 30 is shown in 35. Preferably, the pitch coil 30 is the pitch that the pitch of each turn changes so that most proximal portions of the core 20 may be strongly rolled for a coil and the coil 30 may have the open volume shown in 35 near the distal end of the core 20. By changing the pitch of the coil 30, the guidewire 10 may have a more flexible distance portion.
[0020]
Or the coil 30 may be produced from the coil wire of the many textiles wound around intersection, or the single coil wire of many textiles. The coil wound around intersection of many textiles is indicated to US,4,932,419,B of de Toledo, and is applied as reference. The multi-textiles coil wound around intersection is arranged around the 1st inside coil of two or more coil wires wound around the 1st spiral direction, and the 1st coil, and becomes essential from the 2nd outside spring of two or more coils wound around the 2nd reverse spiral direction. When a core wire is applied to torque as for a wrap coil, it winds and there is a tendency to conserve energy rather than transmitting torque. While it seldom winds, therefore the proximal tip of a wire rotates, a multi-textiles coil decreases the potential at the tip of distance of a wire, and moves suddenly (whip).
[0021]
Combining the core 20 with the coil 30 improves the torque transmission of the guidewire 10 again. It is combined with the core 20 along with the length of the core 20, and the coil 30 may be profit or a separate portion. Combination may be attained by various methods including adhesion, soldering, welding, sticking by pressure, and swaging. Do welding by publicly known arbitrary art in the field concerned including the spot welding or resistance welding which uses

laser, ball (ball) welding using laser, or plasma arc welding. He does soldering by publicly known art in the field concerned, and it must include the process of preparing the surface of the Nitinol core 20 by plating or etching. Preferably, the coil 30 is combined with the core 20 by laser spot welding, and the necessity of preparing the surface of the core 20 by this is excepted. Since he does laser spot welding by coating, it is advantageous again.

[0022]

The method of the substitution which combines the coil 30 with the core 20 is providing the stainless steel hypo tube (hypotube) (not shown) which has an inside diameter of the size for it being close and being in agreement with the surroundings of the core 20. Subsequently, a stainless steel hypo tube may be stuck to the core 20 by pressure, and the coil 30 may be wound around the surroundings of a hypo tube. Subsequently, a hypo tube provides the surface easily combined with the stainless steel coil 30 all the time using the conventional method. A metallic foil or other materials may be used again as an intermediate which makes easy combination between the coil 30 and the core 20.

[0023]

The polymer jacket (jacket) 40 at the tip of distance is used for another coupling method. Polymer may be applied with the form with which polymer may flow between a coil and a core. Combination of the high integrity which is useful to combine that a polymer jacket separates polymer from the coil 30 with ****, and to combine a coil with the core 20 is provided. In addition to these improvements, polymer coating performs better transfer into the distance portion 25 from the core 20. The tip combined with this form provides the further improvement by making the difference in the tone between a coil wire and polymer further. These differences work as a stripe for detection of the guidewire advance in an endoscope use.

[0024]

The distance portion 25 of the core wire 20 is further provided with the polymer tip 40. The polymer tip 40 is useful for some functions. The polymer tip 40 improves the flexibility of the distance portion 25 of the core wire 20. Selection of polymer for the polymer tip 40 changes the flexibility of the distance portion 25 of the core wire 20. For example, the polymer which has a low durometer or hardness makes a very flexible or pliant tip. On the contrary, the polymer which has a high durometer makes a hard wire top end.

[0025]

The polymer tip 40 provides the tip of non-traumatism by the guidewire 10 again. Since the tip of non-traumatism passes along vulnerable body passages, it is suitable good. Finally, the polymer tip 40 works as a binder of non-[radioactive] transmission materials. Carrying the polymer which has non-[radioactive] transmission materials, it is well-known in the field concerned, he is for this making the bright picture under a fluoroscopy mirror, and the user of the guidewire 10 can understand more the place where the distance portion 25 of the guidewire 10 is arranged at a patient's body to fitness by this. Tungsten, platinum, and iridium are mentioned to a suitable radiopacity material of a medical-application grade.

[0026]

Urethane, **** elastic nylon of Pebax, silicone, and a copolymer are mentioned to a suitable polymer nature material for the polymer tip 40. The polymer tips 40 may be single polymer, two or more layers, or the blend of polymer.

[0027]

Use coating (not shown) as the wire of the juxtaposition at the tip 40 of polymer. Hydrophobic coating like fluoropolymers provides the dry lubricity (dry lubricity) which improves the

handling of a guidewire, and exchange of a device. The 2nd lubricative polymer (not shown) coats the distance portion 25 of the guidewire 10, or the wire 10 whole. Lubricative coating improves maneuverability drivability and improves obstacle intersection capability (lesioncrossing capability). Suitable lubricative polymer is well-known in the field concerned, and may contain hydrophilic polymer.

[0028]

The guidewire 10 may include further colored coating. A colored guidewire is indicated to US,5,739,779,B of Rowland in detail, and is used for it as reference in this Description. Generally, the colored coating can improve the visibility of a guidewire, when used in an endoscope procedure. Do stripe attachment again. By stripe attachment, a surgeon can judge a motion and position of a wire. Stripe attachment may be attained by spraying and coating various colors on the wire 10. The option which attaches a stripe to the wire 10 is coating the wire of the coil 30, before winding.

[0029]

Drawing 2 shows the 2nd embodiment of a highly efficient coil wire, and a number with a similar similar element is attached here. If the advantage of all the designs, the material of composition, and a manufacturing method are not clearly changed to below, they are similar to the above-mentioned thing. The guidewire 10 comprises the inner substance core 20 enclosed by the coil 30. The distance portion 25 of the core 20 may be made into tapered shape as mentioned above, or is not preferably made into tapered shape. It is similar with the embodiment of drawing 1, and the distance portion 35 of the coil 30 changes a pitch, in order to provide a more flexible low traumatic tip.

[0030]

The guidewire 10 can be provided with the still more round tip 37. The tip 37 may be polymer nature or may be a metal tip welded to the distance portion 35 of the coil 30. Unlike a usual spring tip guidewire, the guidewire 10 does not have a safe ribbon which connects the core 20 at the tip 37. Instead, the guidewire 10 may contain the polymer 40 and this may be passed in the space between the coils 35, and the space between the distance portion 25 and the tip 37. Suitable polymer is indicated above and the selection of polymer can control the flexibility at a tip here. The polymer 40 may be loaded with radiation non-transmission materials again. Finally, the guidewire 10 may be coated as mentioned above and may contain various colors or stripes. By it, the distance portion of the guidewire 10 is provided with a very pliant tip, and this uses the polymer 40 as a safe ribbon instead of a metallic safe ribbon. The guidewire 10 is provided with the advantage that the core 20 does not need to be ground.

[0031]

Although this Description indicates a desirable design, material, a manufacturing method, and directions for use, a person skilled in the art understands the range and pneuma of this invention with reference to the above-mentioned Claims.

[Brief Description of the Drawings]

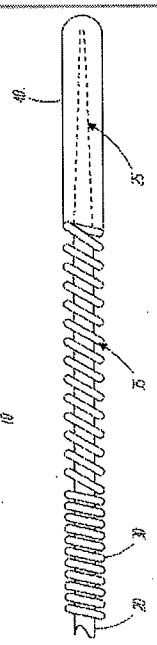
Drawing 1 is the first section of a guidewire.

Drawing 2 is the 2nd section of a guidewire.

CLAIMS

[Claim(s)]
[Claim 1]It is a guidewire and this guidewire is the following. : A thin long core which comprises a nickel titanium alloy; it reaches. A guidewire provided with a coil which comprises the 2nd material and encloses a substantive part of this core.
[Claim 2]The guidewire according to claim 1 in which said nickel titanium alloy contains superelasticity metal.
[Claim 3]The guidewire according to claim 1 in which said nickel titanium alloy contains straight-line elastic metal.
[Claim 4]The guidewire according to claim 1 in which said 2nd material contains a nickel titanium alloy.
[Claim 5]The guidewire according to claim 4 in which said nickel titanium alloy includes a hyperelastic material.
[Claim 6]The guidewire according to claim 4 in which said nickel titanium alloy contains straight-line elastic metal.
[Claim 7]The guidewire according to claim 1 in which said 2nd material contains stainless steel.
[Claim 8]The guidewire according to claim 1 in which said 2nd material contains a precipitation-hardening alloy.
[Claim 9]The following [it is the guidewire according to claim 1];
A guidewire further provided with a polymer tip which encloses a distance portion of said core wire.
[Claim 10]A guidewire which is the guidewire according to claim 9, and said polymer tip is provided with a radiation non-transmission filter, and a distance tip of this guidewire can visualize easily under fluoroscopy by this here.
[Claim 11]The guidewire according to claim 1 containing a wire of a strand with said single coil.
[Claim 12]The guidewire according to claim 1 in which said coil contains many fiber strands.
[Claim 13]The guidewire according to claim 11 in which said wire includes a section of further a ** type.
[Claim 14]The guidewire according to claim 11 in which said wire includes a circular section further.
[Claim 15]The guidewire according to claim 1 in which said coil contains a pitch which changes along with the length of this coil further.
[Claim 16]The guidewire according to claim 15 from which said pitch of said coil changes so that a distal end of this coil may become flexibility from a proximal end part of this coil.
[Claim 17]It is the guidewire according to claim 1, and is the following further. : A guidewire provided with a hypo tube which is connected to said core and combined with said coil.
[Claim 18]The guidewire according to claim 1 by which combination is formed between said coil and said core.
[Claim 19]The guidewire according to claim 18 in which said combination includes welding coupling.
[Claim 20]The guidewire according to claim 18 in which said combination includes an adhesive combination.
[Claim 21]It is a guidewire at a pliant tip and this guidewire is the following.;
A core;

A coil which is a coil of this core which encloses a distance portion at least, and a distal end of this coil elongates to distance of this distance portion of this core;
A tip combined with this distal end of this coil; it reaches. A guidewire provided with a polymer nature safe ribbon which combines this distance portion of this core at this tip.



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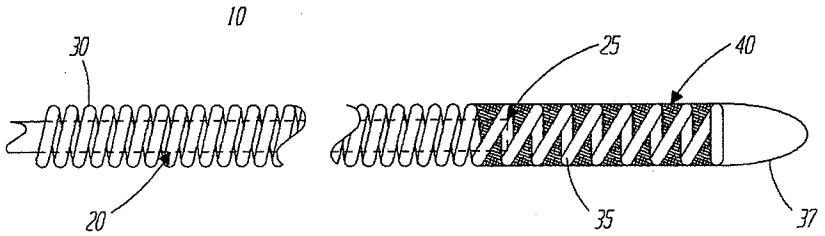

FIG. 2